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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,005	11/14/2001	Hui Ge	14014.0432U2	7848

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NEEDLE & ROSENBERG, P.C.  
SUITE 1000  
999 PEACHTREE STREET  
ATLANTA, GA 30309-3915

EXAMINER

LAM, ANN Y

ART UNIT PAPER NUMBER

1641

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/936,005	GE, HUI	
	<b>Examiner</b>	<b>Art Unit</b>	
	Ann Y. Lam	1641	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 November 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 and 45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 and 45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-11 and 45 are rejected under 35 U.S.C. 102(b) as being anticipated by Kauvar, 5,541,070.

Kauvar discloses a universal protein array, comprising a plurality of substantially pure target polypeptide samples (i.e., antibodies, col. 28, line 41) provided on a solid support (col. 27, lines 64-65), wherein the samples are immobilized on the solid support in an addressable pattern (i.e., array comprising rows and columns of antibody dots, col. 28, lines 39-40).

As to claim 2, the target polypeptide samples maintain a substantially native protein configuration (col. 8, lines 64-66, and col. 10, lines 7-8, and col. 28, lines 6-9.)

As to claim 3, the target polypeptide samples comprise substantially full-length native proteins (col. 8, lines 64-66, and col. 10, lines 7-8, and col. 28, lines 6-9.)

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As to claim 4, each address contains only one substantially pure target polypeptide (see col. 28, lines 39-41 disclosing 100 rows and 100 columns of dots forming a total array of 10,000 separate individual antibodies.)

As to claim 5, the addresses are arranged in rows and columns (col. 28, lines 39-41.)

As to claim 6, the array is arranged in a computer readable format (col. 28, line 34.)

As to claims 7-9, the array comprises at least 10 polypeptide samples, at least 30 different polypeptide samples or at least 100 different polypeptide samples (col. 28, lines 39-41.) (The Office notes that the limitation "different" is not defined to mean --different types--, therefore the limitation "different" is interpreted to encompass the meaning separate or distinct.)

As to claim 10, the array comprises a microarray (col. 28, lines 39-42.)

As to claim 11, the solid support comprises glass (col. 27, line 64.)

As to claim 45, the plurality of substantially pure target polypeptides are a collection of related proteins and the collection includes proteins expressed in a cell during a particular growth phase or environmental condition (col. 8, lines 18-28.)

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kauvar, 5,541,070, in view of Natesan, 6,015,709.

Kauvar discloses the invention substantially as claimed (see above), except for the polypeptide samples comprising transcriptional factors (claim 12), or specifically TFIIA (claim 13.) Natesan discloses these limitations, i.e., an assay wherein the probe is TFIIA.

Natesan discloses that screening derivatives of AP activation tag for binding to TFIIA can be used to obtain functionally equivalent derivatives of AP activation tag (col. 17, lines 45-47), as would be useful for biological research (col. 1, lines 11-17 and lines 47-51.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide TFIIA as the polypeptide sample in the Kauvar protein array in order to screen for derivatives of AP activation tag because Nateson teaches that such screening provides the advantage of obtaining functionally equivalent derivatives of AP activation tag, as would be useful for biological research.

***Response to Arguments***

Applicant's arguments filed November 4, 2006 have been fully considered but they are not persuasive.

Applicant argues that Kauvar fails to teach or suggest an array comprising **substantially pure** target polypeptide samples. Applicant argues that the array of Kauvar in column 28, lines 6-7 does not comprise substantially pure polypeptide samples. Applicant also argues that Natesan also does not disclose substantially pure target polypeptide samples, wherein the polypeptides are those enumerated in claim 12.

The arguments are not persuasive because Applicant's specification does not give a strict definition of "substantially pure" (nor "pure" nor "purified"), but rather gives only examples. Page 15 of Applicant's specification states that the term purified is "intended as a relative term. Thus, **for example**, a purified protein preparation is one in which the specified protein is more enriched than the protein is in its generative environment, for instance within a cell or in a biochemical reaction chamber. A preparation of substantially pure protein **may** be purified such that the desired protein represents at least 50% of the total protein content of the preparation..." (see page 15, lines 3-7, emphasis added.) Thus, because of Applicant's use of the terms "for example" and "may", the specification is not limiting "purified" to those descriptions above. That is, Applicant's specification does not require a strict percentage of the polypeptides in order for it to be considered "substantially pure".

Thus, Applicant's specification does not exclude the polypeptide samples obtained by the technique disclosed by Kauvar in column 27, lines 14-53, i.e., from

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antibody-secreting immortalized cells. (Also, it is well known in the art that this technique provides substantially pure polypeptides). Likewise, Natesan teaches use of the polypeptides probes as recited in claims 12 and 13, and also teaches that probes may be monoclonal antibodies (see for example column 28, lines 37-39). In short, because Applicant does not give a definition of purified, but rather only examples, the polypeptides in Kauvar and Natesan are considered substantially pure.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

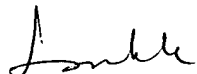
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.L.



**LONG V. LE**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**  
11/79/06